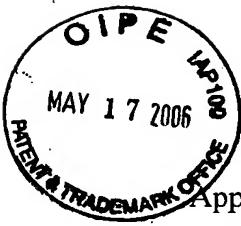


**Express Mail No.: EV 841 454 855 US**



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of: Ronald J. Pettis

Confirmation No.: 6947

Application No.: 10/650,039

Group Art Unit: 1648

Filed: August 28, 2003

Examiner: Humphrey, Louise Z. Wang

For: METHOD OF CONTROLLING  
PHARMACOKINETICS OF  
IMMUNOMODULATORY COMPOUNDS

Attorney Docket No.: 11219-060-999

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §1.56 AND §1.97**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 and §1.97 to inform the United States Patent and Trademark Office (“USPTO”) of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of any claim of the application, Attorneys for Applicant hereby invite the Examiner’s attention to references A04-A50, B01-B18 and C01-C38 listed on the attached form entitled “List of References Cited by Applicant.”

Copies of references A50, B01-B18 and C01-C38 are submitted herewith. Copies of references A04-A49 are not submitted herewith because they are U.S. patents or U.S. patent application publications. Pursuant to 37 C.F.R. § 1.98 (a)(2)(i) as amended (*see* Fed. Reg. vol. 69, no. 182, Sept. 21, 2004), the requirement for providing a copy of each U.S. patent or U.S. patent application publication listed in an Information Disclosure Statement in a patent application, regardless of the filing date of the application, is eliminated.

Identification of the listed references is not meant to be construed as an admission of Applicant or Attorneys for Applicant that such references are available as “prior art” against the subject application.

Applicant respectfully requests that the Examiner review the foregoing references and that the references be made of record in the file history of the application.

Pursuant to 37 C.F.R. § 1.97(b)(4), Applicant believes that no fee is due in connection with the filing of this Information Disclosure Statement. However, should the Patent Office determine otherwise, please charge the necessary fee to Jones Day Deposit Account No. 50-3013. A duplicate of this sheet is enclosed.

Respectfully submitted, by: Jacqueline Benn

Reg. No. 43,492

30,742

(Reg. No.)

Date: May 17, 2006

Laura A. Coruzzi

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Enclosure

<b>LIST OF REFERENCES CITED BY APPLICANT</b> (Use several sheets if necessary)		ATTY. DOCKET NO.	APPLICATION NO.
		11219-060-999	10/650,039
APPLICANT Ronald J. Pettis			
FILING DATE August 28, 2003		ART UNIT	1648

*MAY 17 2006*

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT FIGURES APPEAR
A04	3,814,097	06/04/74	Ganderton, et al.	
A05	3,964,482	6/22/76	Gerstel, et al.	
A06	4,270,537	06/02/81	Romaine	
A07	4,592,753	06/03/86	Panoz	
A08	4,886,499	12/12/89	Cirelli, et al.	
A09	5,003,987	4/2/91	Grinwald	
A10	5,098,389	03/24/92	Cappucci	
A11	5,156,591	10/20/92	Gross, et al.	
A12	5,250,023	10/5/93	Lee, et al.	
A13	5,279,544	01/18/94	Gross, et al.	
A14	5,417,662	05/23/95	Hjertman, et al.	
A15	5,527,288	06/18/96	Gross, et al.	
A16	5,582,591	12/10/96	Cheikh	
A17	5,591,139	1/7/97	Lin, et al.	
A18	5,800,420	09/98	Gross, et al.	
A19	5,801,057	9/1/98	Smart, et al.	
A20	5,820,622	10/13/98	Gross, et al.	
A21	5,848,990	12/15/98	Cirelli, et al.	
A22	5,848,991	12/15/98	Gross, et al.	
A23	5,876,582	3/2/99	Frazier	
A24	5,879,326	3/9/99	Godshall, et al.	
A25	5,928,207	7/27/99	Pisano, et al.	
A26	5,957,895	9/28/99	Sage, et al.	
A27	6,007,821	12/28/99	Srivastava, et al.	
A28	6,056,716	05/2/00	D'Antonio, et al.	
A29	6,099,504	08/08/02	Gross, et al.	
A30	6,200,291	03/13/01	Di Pietro	
A31	6,319,224	11/20/01	Stout, et al.	
A32	6,334,856	01/01/02	Allen, et al.	
A33	6,346,095	02/12/02	Gross, et al.	

EXAMINER NYJD-1605547v1	DATE CONSIDERED
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	FILING DATE August 28, 2003	ART UNIT 1648

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT FIGURES APPEAR
	A34	6,482,176	11/19/02	Wich	
	A35	6,537,242	03/25/03	Palmer, Phyllis J.	
	A36	US 2002/0095134	07/18/02	Pettis, et al.	
	A37	US 2002/0156453	10/24/02	Pettis, et al.	
	A38	US 2003/0073609	4/17/03	Pinkerton	
	A39	US 2003/0100885	5/29/03	Pettis, et al.	
	A40	US 2004/0028707	02/12/04	Pinkerton	
	A41	US 2004/0073160	04/15/04	Pinkerton	
	A42	US 2004/0170654	09/02/04	Pinkerton	
	A43	US 2004/0175360	09/09/04	Pettis, et al.	
	A44	US 2004/0175401	09/09/04	Pinkerton	
	A45	US 2005/0008683	01/13/05	Mikstza, et al.	
	A46	US 2005/0096330	05/05/05	Pettis	
	A47	US 2005/0096331	05/05/05	Pettis	
	A48	US 2005/0096332	05/05/05	Pettis	
	A49	US 2005/0256499	11/17/05	Pettis, et al.	
	A50	09/606,909	6/29/00	Pettis	

**FOREIGN PATENT DOCUMENTS**

		FOREIGN PATENT DOCUMENT COUNTRY CODE, NUMBER, KIND CODE (IF KNOWN)	DATE	NAME	PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT FIGURES APPEAR	T
	B01	WO 94/23777	10/27/94	Elan Medical Technologies Limited		
	B02	WO 96/17648	06/13/96	Cibageigy AG		
	B03	EP 0 429 842	08/28/96	Korea Research Institute of Chemical Technology		
	B04	WO 96/37256	11/28/96	Silicon Microdevices, Inc.		
	B05	WO 96/37155	11/28/96	Silicon Microdevices, Inc.		
	B06	WO 97/21457	06/19/97	Elan Medical Technologies Limited		
	B07	WO 99/43350	09/02/99	Iomai Corporation		
	B08	WO 99/64580	12/16/99	Georgia Tech Research Corporation		

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B09	WO 00/09186		02/24/00	Medi-Ject Corporation		
B10	WO 00/67647		11/16/00	Scimed Life Systems, Inc.		
B11	WO 00/74763		12/14/00	Georgia Tech Research Corporation		
B12	EP 1 086 718		03/28/01	Becton, Dickinson, and Company		
B13	EP 1 086 719		03/28/01	Becton, Dickinson, and Company		
B14	EP 1 088 642		04/04/01	Becton, Dickinson, and Company		
B15	EP 1 092 444		04/18/01	Becton, Dickinson, and Company		
B16	WO 02/11669		02/14/02	Antigenics, LLC		
B17	WO 02/083232		10/24/02	Becton, Dickinson, and Company		
B18	WO 03/002175		01/09/03	Pharmacia Corporation		

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)	T
C01		AGRAWAL, et al., Pharmacokinetics, Biodistribution, and Stability of Oligodeoxynucleotide Phosphorothioates in Mice, Proc. Natl. Acad. Sci. USA, Vol. 88, pp. 7595-7599, September 1991 Medical Sciences	
C02		AUTRET, et al., Comparison of Pharmacokinetics and tolerance of Calcitonine administered by Intradermal or Subcutaneous Route, Fundamental Clinical Pharmacology, Vol. 3, No. 2, pp 170-171, 1989	
C03		AUTRET, et al, [Comparison of plasma concentration and tolerance of a single dose of human calcitonin by intradermal and subcutaneous administration], Therapie 46(1):5-8, 1991	
C04		BENONI, et al., Distribution of Ceftazidime in Ascitic Fluid, Antimicrobial Agents and Chemotherapy, Vol. 25, No. 6, June 1984, pp. 760-763	
C05		BICKERS, et al., editors, Clinical Pharmacology of Skin Disease, pp. 57-90, Churchill Livingstone, Inc. 1984	
C06		BOCCI, et al., The Lymphatic Route. IV. Pharmacokinetics of Human Recombinant Interferon a2 and Natural Interferon beta Administered Intradermally in Rabbits, International Journal of Pharmaceutics, 32, 1986, pp. 103-110 Elsevier Science Publishers B.V. (Biomedical Division)	
C07		BRESSOLLE, et al., A Weibull distribution model for intradermal administration of ceftazidime," J. Phar. Sci. 82(11):1175-8, 1993	
C08		BRONAUGH RL, et al., Methods for in Vitro Percutaneous Absorption Studies. II. Animal Models for Human Skin. Toxicol Appl. Pharmacol. 1982 Mar 15;62(3):481-8.	
C09		BURKOTH, et al., Transdermal and Transmucosal Powered Drug Delivery, Critical Review™ in Therapeutic Drug Carrier Systems, 16 (4), (1999), pps. 331-384	
C10		CALLEN, Intralesional Corticosteroids, Journal of the American Academy of Dermatology, University of Louisville School of Medicine, pp. 149-151, 1981	
C11		CORBO M., et al, Transdermal Controlled Delivery of Propranolol from a Multilaminate Adhesive Device. Pharm Res. 1989 Sep;6(9):753-8.	
C12		COSSUM, et al., Disposition of the C-Labeled Phosphorothioate Oligonucleotide ISIS 2105 after Intravenous Administration to Rats, The Journal of Pharmacology and Experimental Therapeutics, pp. 1181-1190, Vol. 267,	

EXAMINER NYJD-1605547v1	DATE CONSIDERED
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Examiner Initials	(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)	T
	No. 3, 1993	
C13	COSSUM, et al., Pharmacokinetics of C-Labeled Phosphorothioate Oligonucleotide, ISIS 2105 after Administration to Rats, The Journal of Pharmacology and Experimental Therapeutics, pp. 89-94, Vol. 269, No. 1, 1994	
C14	CROOKE, et al., A Pharmacokinetic Evaluation of C-Labeled Afovirsen Sodium in Patients with Genital Warts, Clinical Pharmacology & Therapeutics, pp. 641-646, Vol. 56, No. 6, Part 1, December 1994	
C15	FIROOZ, et al., Benefits and Risks of Intralesional Corticosteroid Injection in the Treatment of Dermatological Diseases, pp. 363-370, Vol. 20, No. 5, Clinical and Experimental Dermatology, Blackwell Science Ltd, September 1995	
C16	GOODARZI, et al., Organ Distribution and Stability of Phosphorothioated Oligodeoxyribonucleotides in Mice, Biopharmaceutics & Drug Disposition, pp. 221-227, Vol. 13, No. 3, John Wiley & Sons Ltd., April 1992	
C17	HALPERIN, et al., A comparison of the intradermal and subcutaneous routes of influenza vaccination with A/New Jersey/76 (swine flu) and A/Victoria/75: report of a study and review of the literature. Am. J. Public Health. 1979 Dec;69(12):1247-50	
C18	HAYNES, et al., Ultra-long-duration Local Anesthesia Produced by Injection of Lecithin-coated Methoxyflurane Microdroplets, Anesthesiology, Vol. 63, Vol. 5, pp. 490-499, Nov. 1985	
C19	HENRY, et al., Microfabricated Microneedles: A Novel Approach to Transdermal Drug Delivery, Journal of Pharmaceutical Sciences, Vol. 87, No. 8, August 1998, pps. 922-925	
C20	JAKOBSON et al., Variations in the Blood Concentration of 1,1,2-Trichloroethane by Percutaneous Absorption and Other Routes of Administration in the Guinea Pig, Vol. 41, No. 5, pp. 497-506, Acta Pharmacologica et Toxicologica, November 1977	
C21	JARRATT, et al., The Effects of Intradermal Steroids on the Pituitary-Adrenal Axis and the Skin, The Journal of Investigative Dermatology, Vol. 62, No. 4, pp. 463-466, 1974	
C22	KAUSHIK, et al., Transdermal Protein Delivery Using Microfabricated Microneedles, Oct/Nov 1999 (1 page)	
C23	KIRKPATRICK, et al., Local Anesthetic Efficacy of Methoxyflurane Microdroplets in Man, Vol. 67, No. 3A, Anesthesiology, September 1987	
C24	LEROY, et al., Pharmacokinetics of Ceftazidime in Normal and Uremic Subjects, Antimicrobial Agents and Chemotherapy, Vol. 25, No. 5, pp. 638-642, May 1984	
C25	MARIAN, et al., 2001, Acta Biologica Hungarica, 52(1): 35-45	
C26	MCALLISTER, et al., Three-Dimensional Hollow Microneedle and Microtube Arrays, Conference: Solid-State Sensors and Actuators Transducers-Conference, 1999;10 <sup>th</sup> , Vol. 12., pp 1098-1103	
C27	MCALLISTER, et al., Solid and Hollow Microneedles for Transdermal Protein Delivery, Proceed. Int'l. Symp. Control. Rel. Bioact. Mater., 26 (Revised July 1999) Controlled Release Society, Inc. pp. 192-193	
C28	MCGUGAN, et al., Adrenal Suppression from Intradermal Triamcinolone. The Journal of Investigative Dermatology, Vol. 40, pp. 271-272, Baltimore, MD., 1963	
C29	Merriam-Webster's Collegiate Dictionary, 10 <sup>th</sup> Edition, 1998, Merriam-Webster, Inc., Springfield, MA, p. 306	
C30	SCOTT, et al., Toxicity of Interferon, Vol. 282, pp. 1345-1348, British Medical Journal, April 25, 1981	
C31	SUPERSAXO, et al., Recombinant Human Interferon Alpha-2a: Delivery to Lymphoid Tissue by Selected Modes of Application, Pharmaceutical Research, Vol. 5, No. 8, pp. 472-476, August 1998	
C32	SUTHEREST, Treatment of Pruritus Vulvae by Multiple Intradermal Injections of Alcohol. A Double-Blind Study, Vol. 86, pp. 371-373, British Journal of Obstetrics and Gynecology, May 1979	
C33	SVEINSSON, 1939, Investigation on the Influence of Insulin and Adrenalin in Rabbits with Alimentary Fatty Liver and Muscles and on the Content of Fat and Sugar in Blood, Oslo, Norway (pp. 66-86)	
C34	The American Heritage College Dictionary, 2000, 3 <sup>rd</sup> Edition; Houghton Mifflin Company, Boston, New York, p. 368	

EXAMINER	DATE CONSIDERED
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	C35	The Merck Manual of Diagnosis and Therapy, 1999, 17 <sup>th</sup> Edition, Beers & Berkow, ed., Merck Research Laboratories, Division of Merck & Co., Inc., Whitehouse Station, NJ, pp. 2559-2567	
	C36	WARD, et al., Puritus Vulvae: Treatment by Multiple Intradermal Alcohol Injections, Vol. 93, No. 2, pp. 201-204, British Journal of Dermatology, August 1975	
	C37	WU, et al., Pharmacokinetics of Methoxyflurane after its Intra-Dermal Injection as Lecithin-Coated Microdroplets, Vol. 9, pp. 1-12, Journal of Controlled Release, July 1989	
	C38	ZAYNOUN, et al., The Effect of Intracutaneous Glucocorticoids on Plasma Cortisol Levels, Vol. 88, No. 2, pp. 151-156, British Journal of Dermatology, February 1973	

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